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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/574,302	MUELLER-WALZ, RUDI
	Examiner	Art Unit
	NICOLETTA KENNEDY	1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/17/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1 and 3-33 are currently pending.

Priority

This application, filed March 31, 2006, is a national stage entry of PCT/IB04/03481 filed October 8, 2004, and claims foreign priority to United Kingdom application 0323684.1, filed on October 9, 2003. Applicants have provided a certified copy of the United Kingdom application.

Maintained Rejection

Statutory Type Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. The rejection of claim 20 as being provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 20 of copending application no. 10/574,334 is maintained.

The claims are identical in each application. Each is directed to a pharmaceutical aerosol formulation for use in a metered dose inhaler (MDI) comprising formoterol

fumarate di-hydrate in suspension, a propellant and ethanol, wherein the moisture content of the formulation is in the range of from 50 ppm to 800 ppm.

Response to Arguments

Applicant's arguments filed May 17, 2011 have been fully considered but they are not persuasive. Applicant states that he will address the rejection at such time as one of the conflicting claims is deemed allowable. However, the claims are still not patentably distinct and thus the rejection is maintained.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. The rejection of claims 20-23, 27 and 33 under 35 U.S.C. 103(a) as being unpatentable over Blondino et al. (US 6,451,285) (issued Sept. 17, 2002) in view of Clarke et al. (US 2002/0103260) is maintained.

Regarding claim 20, Blondino et al. teach suspension aerosol formulations containing formoterol fumarate and a fluoroalkane propellant (title). In one example, an aerosol formulation comprises formoterol fumarate in suspension and HFA-134a wherein the formulation has a moisture content of 428.91 ppm (example 10 and Table 4, showing data for example 10). Ethanol may be included as a solvent and is the most preferred solvent (column 2, line 60 to column 3, line 1).

However, Blondino et al. do not teach that the formoterol fumarate weak acid form may be formoterol fumarate di-hydrate. Clarke et al. cure this deficiency.

Clarke et al. teach an aerosol composition for a metered dose inhaler comprising formoterol fumarate di-hydrate, ethanol, and HFA 134a (para. 0024).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Blondino et al. with those of Clarke et al. One of ordinary skill would have been motivated to do so with regard to Clarke et al. teach a specific aerosol composition comprising formoterol fumarate di-hydrate, a weak acid formoterol salt generally disclosed by Blondino et al.

Regarding the language “consisting essentially of,” MPEP 2111.03 states that “For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355.

Regarding claims 21-22, 27 and 33, Blondino et al. teach that the formulation is placed in an aluminum metered dose inhaler canister (examples 1-3 and 10).

Regarding claim 23, Blondino et al. teach that an effective amount of formoterol fumarate is about 12 micrograms per activation (column 3, lines 51-55).

Response to Arguments

Applicant's arguments filed May 17, 2011 have been fully considered but they are not persuasive. Applicant first argues that neither Blondino nor Clarke provide the skilled person with the necessary direction to make the claimed formulation with a reasonable expectation of success (remarks, p. 2). Applicant argues that because the formulation consists predominantly of the dihydrate form, the references are inapplicable (remarks, p. 3). However, “consists predominantly" does not exclude other forms of formoterol fumarate and thus supports the interpretation that the language “consisting essentially of” includes other forms of the formoterol fumarate than the di-hydrate form.

Applicant points to the declarations filed 3/18/10 and 11/22/10. While these do show that the di-hydrate exists at a certain water content, there is no showing of increased stability of the di-hydrate form over a combination of fumarate forms. Even if such a showing was made, the showing would not be commensurate in scope with the instant claims since the instant claims do not limit the fumarate to only the di-hydrate form.

6. The rejection of claims 1, 7, 10, 13-17, 21, 23-24, 27-28 and 32 under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. (US 2002/0103260) is maintained.

Regarding claims 1, 7 and 28, Clarke et al. teach an aerosol composition for a metered dose inhaler comprising formoterol fumarate di-hydrate, ethanol, and HFA 134a (para. 0024). Clarke et al. further teach that the aerosol composition for a metered dose inhaler is comprised of formoterol fumarate di-hydrate, fluticasone propionate, a steroid (para. 0024). The steroid may be in solution in the propellant (claim 7). The formoterol may be present in **a** specific crystalline form, in the form of **a** hydrate, especially in the form of fumarate di-hydrate (para. 0010 and claim 4).

However, Clarke et al. fail to teach one embodiment teachings each of the instant claim limitations. The broad teachings of Clarke et al. cure this deficiency.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the broad teachings of Clarke et al. to have used formoterol fumarate di-hydrate as the only form of formoterol present in a formulation comprising a formoterol form, ethanol, fluticasone propionate and HFA 134a. One would have been motivated to do so because Clarke et al. teach that a specific crystalline form, including the di-hydrate form, may be the form present.

With regard to the water content, Clarke et al. teach that the formoterol may be present especially in the form of formoterol fumarate di-hydrate. The use of “a specific form” indicates that only a singular form may be present and if only the di-hydrate form is present, then the water content must necessarily be between 4.28 and 4.8% by weight.

Regarding the language “consisting essentially of,” MPEP 2111.03 states that “For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103,

absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355.

Regarding claim 10, Clarke et al. teach that the formoterol fumarate di-hydrate is present at 0.012% by weight of the composition (para. 0024).

Regarding claims 13-15, and 32, Clarke et al. teach that the aerosol composition comprises HFA 134a and HFA 227, both hydrofluoroalkanes (para. 0024).

Regarding claim 16, Clarke et al. teach that the propellants (HFA 134a and HFA 227) are present at 97.238% by weight of the composition (para. 0024).

Regarding claim 17, Clarke et al. teach that ethanol is present at 2.5000% by weight of the composition (para. 0024).

Regarding claim 21, Clarke et al. teach that the inhalation device may be an aerosol vial (para. 0015).

Regarding claim 23, Clarke et al. teach that the metered dose inhaler may deliver 6 to 24 micrograms of formoterol fumarate di-hydrate (para. 0017). MPEP 2144.05 states that “[i]n the case where the claimed ranges ‘overlap or lie inside ranges disclosed by the prior art’ a *prima facie* case of obviousness exists” quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed range overlaps the range taught by Clarke et al. and is therefore prima facie obvious.

Regarding claim 24, Clarke et al. teach that the metered dose inhaler may deliver from 25 to 500 micrograms of fluticasone propionate di-hydrate (para. 0017). MPEP 2144.05 states that “[i]n the case where the claimed ranges ‘overlap or lie inside ranges

disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed range overlaps the range taught by Clarke et al. and is therefore prima facie obvious.

Regarding claim 27, Clarke et al. teach that the aerosol vial may be a metered dose inhaler (para. 0015).

Response to Arguments

Applicant's arguments filed May 17, 2011 have been fully considered but they are not persuasive. Applicant first argues that Clarke teaches only one aerosol formulation but 215 dry powder formulations (remarks, p. 4). However, this is immaterial to the fact that Clarke does teach aerosol formulations and may be relied upon for this teaching. Further, Applicant argues that Clarke does not teach the water content of the formoterol fumarate dihydrate (remarks, p. 4). However, as stated in the rejection, for the dihydrate form to exists, the water content must be the same as that claimed since a product and its properties cannot be separated. Clarke teaches that the crystalline form may be the dihydrate form and is thus enabled for having the dihydrate form present.

Applicant also argues that construing "consisting essentially of" as "comprising" is erroneous. However, "consists predominantly" does not exclude other forms of formoterol fumarate and thus supports the interpretation that the language "consisting essentially of" includes other forms of the formoterol fumarate than the di-hydrate form.

Applicant points to the declarations filed 3/18/10 and 11/22/10. While these do show that the di-hydrate exists at a certain water content, there is no showing of increased stability of the di-hydrate form over a combination of fumarate forms. Even if

such a showing was made, the showing would not be commensurate in scope with the instant claims since the instant claims do not limit the fumarate to only the di-hydrate form.

With regard to claim 17, Applicant argues that ethanol must be present in amounts of less than 2.5% by weight (remarks, p. 5). However, the claim of record does not claim this limitation. In the claim set filed November 22, 2010, the claim reads "the formulation according to claim 1 wherein the ethanol is present in amounts of 1% to 8% by weight." Thus, the teaching of ethanol present at 2.5% by weight of Clarke renders this claim obvious.

7. The rejection of claims 3-6, 21-22, 26 and 33 under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. (US 2002/0103260) as applied to claims 1, 7, 10, 13-17, 21, 23-24, 27-28 and 32 above, and further in view of Kordikowski et al. (US 2003/0223939) is maintained.

Clarke et al. teach each limitation of claim 1, from which claims 3-6 depend. However, these references fail to teach the fine particle fraction of the delivered dose of formoterol fumarate di-hydrate or steroid. Kordikowski et al. cure this deficiency.

Regarding claims 3 and 5, Kordikowski et al. teach particulate suspensions comprising active substances in particulate form suspended in hydrofluoroalkane propellants for use in metered dose inhalers (abstract). These suspensions are stored at 75% relative humidity and at 40°C (para. 0095) for varying periods of time, include 6 months (para. 0080). The fluid suspensions allow the aerosol formulations used in metered dose inhalers to give a more uniform dosing rate throughout the useable life of

the inhaler (para. 0081). The relative standard deviation in the quantity of active substance delivered in each dose is no more than 15% (para. 0084). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). This "no more than 15%" parameter disclosed by Kordikowski et al. fits within the variance of +/- 25% and the claimed range is therefore prima facie obvious.

Regarding claims 4 and 6, Kordikowski et al. teach particulate suspensions comprising active substances in particulate form suspended in hydrofluoroalkane propellants for use in metered dose inhalers (abstract). Kordikowski et al. specifically teach that fluticasone propionate in HFA 134a (Figure 5) and formoterol fumarate di-hydrate (para. 0096) have a fine particle fraction of 35% (paras. 0020 and 0132). This fine particle fraction is delivered through a metered dose inhaler (para. 0021).

Regarding claims 21-22 and 33, Kordikowski et al. teach that the aluminum metered dose inhaler need not be coated (paras. 0139-0141).

Regarding claim 26, Kordikowski et al. teach that the relative standard deviation in the quantity of active substance delivered in each dose is preferably no more than 15% (para. 0084). Although Kordikowski et al. does not specifically state that this active substance doseage is stated on the label, it is well known in the art that inhaler labels specify the quantity of active substance delivered in each dose.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Clarke et al. with those of

Kordikowski et al. with regard to claims 4 and 6, to formulate a composition with a fine particle fraction of at least 35%. One of ordinary skill would have been motivated to do so because a fine particle fraction of at least 35% will result in more efficient delivery of the active substance to the deep lung (Kordikowski et al., para. 0133). With regard to claims 3, 5 and 26, one of ordinary skill in the art would have been motivated to have a variance of no more than +/-25% of the mean delivered dose because this improves the accuracy of the dosage amount. Additionally, with regard to claims 21-22 and 33, Kordikowski et al. teach a method of improving flocculation behavior such that less ethanol than usual is required as a co-solvent and such that the aluminum metered dose inhaler need not be coated, simplifying the manufacturing process for an aerosol metered dose inhaler composition.

Response to Arguments

Applicant's arguments filed May 17, 2011 have been fully considered but they are not persuasive. Applicant argues that Kordikowski et al. fails to remedy the deficiency of Clarke et al. Because the rejection based on Clarke et al. has been maintained, this rejection is maintained as well.

8. The rejection of claims 8-9, 11-12, 18-19, 25 and 29-31 under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. (US 2002/0103260) as applied to claims 1, 7, 10, 13-17, 21, 23-24, 27-28 and 32 above, and further in view of Keller et al. (US 6,475,467) is maintained.

Clarke et al. teach each limitation of claim 1, from which claims 8-9, 11-12 and 18-19 depend, each limitation of claim 13, from which claims 29 and 31 depend, and

each limitation of claim 21, from which claim 25 depends. However, Clarke fails to teach that salts of cromoglycic acid and or nedocromil may be used in the formoterol fumarate di-hydrate composition. Additionally, Clarke fails to teach that fluorochlorocarbons such as F218 may be used as the propellant. Finally, Clarke fails to teach that ciclesonide may be used in combination with formoterol fumarate di-hydrate. Instead, Clarke teaches the efficacious amounts and weight % by weight of the composition for the steroid fluticasone propionate. Keller et al. cure these deficiencies.

Regarding claim 8, Keller et al. teach that a combination of formoterol and ciclesonide may be suspended in an aerosol composition (column 5, lines 40-47).

Regarding claim 9, Keller et al. teach that the active compounds may comprise from 0.0001 to 0.2% by weight of the composition (column 6, lines 1-4). In examples where a combination of active compounds are used, the steroid is present in a larger amount than the formoterol. Therefore, the steroid would be from at least 0.00005% to 0.1% by weight of the composition. MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the range in the instant claim overlaps the range disclosed by Keller et al. and is therefore prima facie obvious.

Regarding claim 11, Keller et al. teach the use of pharmaceutically acceptable salts of cromoglycic acid or nedocromil as carriers in an aerosol suspension formulation (abstract). The active compound in the formulation may be formoterol (column 5, line23).

Regarding claim 12, Keller et al. teach that the cromoglycic acid salts or nedocromil salts are present at not over approximately 0.7%, preferably present at 0.007 to 0.36%, and particularly present at 0.015 to 0.15% by weight of the total formulation (column 6, lines 50-56). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed range overlaps the ranges disclosed by the prior art and is therefore prima facie obvious.

Regarding claim 18, Keller et al. teach that the aerosol formulations may contain surface-active agents such as oleic acid, lecithin, sorbitan trioleate, cetylpyridinium chloride, benzalkonium chloride, polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (20) sorbitan monooleate, polyoxypropylene/polyoxyethylene block copolymers, polyoxypropylene/polyoxyethylene/ethylenediamine block copolymers, ethoxylated castor oil and the like (column 9, lines 17-25).

Regarding claim 19, Keller et al. teach that the proportion of surface-active agents, if present, can preferably be approximately 0.0001 to 1% by weight of the formulation (column 9, lines 25-27).

Regarding claim 25, Keller et al. teach that ciclesonide may be used as the pharmaceutically active compound administered as suspension aerosols (column 5, lines 13-15 and line 25). The ciclesonide may be administered in an efficacious dose of approximately 0.1 to 100 micrograms per puff of spray (column 5, lines 56-59). MPEP

2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed range overlaps the ranges disclosed by the prior art and is therefore prima facie obvious.

Regarding claims 29-31, Keller et al. teach that suitable non-toxic liquid propellants for aerosol formulations include trichloro-monofluoromethane (F11), dichlorodifluoromethane (F12), monochlorotrifluoromethane (F13), dichloro-monofluoromethane (F21), monochlorodifluoromethane (F22), monochloromonofluoromethane (F31), 1,1,2-trichloro-1,2,2-trifluoroethane (F113), 1,2-dichloro-1,1,2,2-tetrafluoroethane (F114), 1-chloro-1,1,2,2,2-pentafluoroethane (F115), 2,2-dichloro-1,1,1-trifluoroethane (F123), 1,2-dichloro-1,1,2-trifluoroethane (F123a), 2-chloro-1,1,1,2-tetrafluoroethane (F124), 2-chloro-1,1,2,2-tetrafluoroethane (F124a), 1,2-dichloro-1,1-difluoroethane (F132b), 1-chloro-1,2,2-trifluoroethane (F133), 2-chloro-1,1,1-trifluoroethane (F133a), 1,1-dichloro-1-fluoroethane (F141b) and 1-chloro-1,1-difluoroethane (F142b), alkanes such as *propane* (with regard to instant claim 30), butane and isobutane, fluorinated alkanes such as *octafluoropropane (F218)* (with regard to instant claim 31)(column 7, lines 7-25).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Clarke et al. with those of Keller et al. One of ordinary skill would have been motivated to combine the teachings of Keller et al. with those of Clarke et al. with regard to claims 8-9 and 25 because

Keller et al. teach the simple substitution of a known steroid. One of ordinary skill would have been motivated to do so with regard to claims 11-12 because Keller et al. teach that disodium cromoglycate and nedocromil sodium are used in known metered-dose aerosols in a therapeutically or phophylatically efficacious amount. One of ordinary skill would have been motivated to combine the teachings of Keller et al. with those of Clarke et al. with regard to claims 18-19 because Keller et al. teach that the aerosol formulations may comprise a surfactant to lower the surface tension of the formulation. One of ordinary skill would have been motivated to combine the teachings of Keller et al. with those of Clarke et al. with regard to claims 29-31 because Keller et al. teach the simple substitution of known propellants.

Response to Arguments

Applicant's arguments filed May 17, 2011 have been fully considered but they are not persuasive. Applicant argues that Keller et al. fails to remedy the deficiency of Clarke et al. Because the rejection based on Clarke et al. has been maintained, this rejection is maintained as well.

Double Patenting

9. The rejection of claims 1, 3-19 and 21-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-19 and 21-33 of copending Application No. 10/574,334 in view of Clarke et al. (US 2002/0103260) is maintained.

The only difference between the claims is that the instant claims claim the steroid in solution and the copending claims claim the steroid in suspension. Clarke et al. teach

combinations of formoterol and fluticasone propionate for inhalation wherein the fluticasone propionate (steroid) may be in solution or suspension (title, abstract, claims 1 and 7-8).

It would have been prima facie obvious to have substituted the steroid in suspension of the copending claims for the steroid in solution of the instant claims. One would have been motivated to do so because Clarke et al. teach that having the steroid in solution or suspension is a known modification in the inhalable formoterol and steroid formulation art

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments filed May 17, 2011 have been fully considered but they are not persuasive. Applicant states that he will address the rejection at such time as one of the conflicting claims is deemed allowable. However, the claims are still not patentably distinct and thus the rejection is maintained.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLETTA KENNEDY whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Thursday 11:30 to 8:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Gollamudi Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. K./
Examiner, Art Unit 1611

/Joanne Hama/
Primary Examiner, Art Unit 1632